Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Fluoxetine Therapeutic Effects With Duloxetine in patients with IBS with constipation

Protocol summary

Study aim
Comparison of the therapeutic effects of Fluoxetine with Duloxetine in patients with IBS type of constipation
Design
Randomized clinical trial, single central, parallel with three groups
Settings and conduct
Patients with Irritable bowel syndrome in the age range of 18-45 years who have predominant constipation symptoms and in accordance with Rome2 criteria are diagnosed by gastroenterologist and general specialist from among the referrals to the gastroenterology clinic and general, and all patients Must lack warning signs including diarrhea, weight loss, gastrointestinal bleeding, and the use of drugs, alcohol and drugs. In some cases, patients in any biopsy or physical examination have any symptoms of organic disease, they are excluded from the study
Participants/Inclusion and exclusion criteria
Patients are newly diagnosed with irritable bowel syndrome. People are between the ages of 18-45 who have predominant constipation symptoms and are in accordance with Rome2 criteria. All patients should have no warning signs including diarrhea, weight loss, gastrointestinal bleeding, and the use of drugs, alcohol and drugs. In some cases, patients in any biopsy or physical examination have any signs or symptoms of organic disease, are excluded
Intervention groups
Then, in the first group, dicyclomine is given with fluoxetine 20 mg and the second group is dicyclomine and duloxetine 20 mg and the third group is given only the dicyclomine. Then the questionnaire will be filled by the researcher for them and the patients will be followed up monthly in person and by the phone for two consistent months. The symptoms will be divided by severity into 4 groups, which gives 25 grades to each group.
Main outcome variables
Constipation, abdominal pain , life quality, Flatulence

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20171115037478N1**
Registration date: **2018-02-07, 1396/11/18**
Registration timing: **retrospective**

Last update: **2018-02-07, 1396/11/18**
Update count: **0**
Registration date
2018-02-07, 1396/11/18

Registrant information
Name
Behnam Sajedi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 24 3344 2928
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2017-11-21, 1396/08/30
Expected recruitment end date
2018-01-19, 1396/10/29
Actual recruitment start date
2017-06-21, 1396/03/31
Actual recruitment end date
2017-09-20, 1396/06/29
Trial completion date

empty

Scientific title
Comparison of Fluoxetine Therapeutic Effects With Duloxetine in patients with IBS with constipation

Public title
Fluoxetine Therapeutic Effects With Duloxetine in patients with IBS with constipation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
new cases of irritable bowel syndrome aged 18-45 constipation predominant symptoms consistent with the criteria Rome2 criteria
Exclusion criteria:
patients with night diarrhea patients with weight loss patients with history of GI bleeding patients that use alcohol, drugs and opiums. patients with psychological diseases patients with CNS disorders patients with kidney or liver failure cardica patients
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Actual sample size reached: **162**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of selecting individuals and their placement in triple groups will be randomized, so that after confirmation of the conditions necessary for inclusion in the study patients will be selected sequentially and the first patient in the first group, the second patient in The second group and the third patient will be placed in the third group, and in the same way, again, the groups will take each patient in order to reach the desired level
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zanjan University of Medical Sciences Ethics Committee
Street address
Khorramshahr Street
City
Zanjan
Province
Zanjan
Postal code
۴۵۱۵۶۱۳۱۱۳
Approval date
2017-08-07, 1396/05/16
Ethics committee reference number
ZUMS.REC.1396.93

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome is a type of constipation
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Severity of illness in irritable bowel syndrome, constipation type
Timepoint
At the beginning of the study and two months later
Method of measurement
IBS-SSS(IBS-(Severity scoring system)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: The first group of dicyclomin tablets is given every 8 hours with fluoxetine 20 mg daily for 2 months
Category
Treatment - Drugs

2

Description
Intervention group 2: The second group of dicyclomine tablets is given every 8 hours with duloxetine 20 mg daily for 2 months.
Category
Treatment - Drugs

3

Description
Intervention group 3: The third group of dicyclomine tablets is given every 8 hours 20 mg daily for 2 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital in Zanjan
Full name of responsible person
Sattar Jafari
Street address
Dr. Shariati Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Alireza Shoghli
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Web page address
http://Zums.ac.ir/index.php?slc_lang=fa&sid=3&slct_pg_id=2089
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Behnam sajedi
Position
Resident of Internal Medicine
Latest degree
Medical doctor
Other areas of specialty/work
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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available